



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/250,466 02/16/99 CHUDoba

I RPE-27

EXAMINER

HM22/1229

LUNDGREN, J

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

12/29/00

JOHN B HARDAWAY III
HARDAWAY LAW FIRM
P O BOX 10107
FEDERAL STATION
GREENVILLE SC 29603-0107

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/250,466

Applicant(s)

CHUDоба ET AL.

Examiner

Jeffrey S. Lundgren

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 17-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1-14 and 17-26 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The rejection of claims 1-14, and 17-26 under 35 U.S.C. 112, second paragraph, in the Office Action mailed on July 3, 2000, are overcome by means of amendment in Applicants response received on October 10, 2000.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. The rejection of claims 1-14, 17-24, and 26, under 35 U.S.C. 102(e) as being anticipated by Garini et al (U.S. Patent No. 5,817,462, October 6, 1998), in the Office Action mailed July 3, 2000, is maintained.

Applicants argue particular scenarios of the specification and allege that the instant Application and Garini are different. Applicants argue that in the current invention, the evaluation of the biopolymer with the detector molecules bonded thereto includes the detection and analysis of distinguishable color bands generated, and the plurality of different color ratios resulting from the bonding. Applicants point to page 5, line 13, through page 6, line 2 of the instant specification, and thus conclude that the

Art Unit: 1631

overlap of two differently labeled chromosome fragments bonded to the biopolymer will yield three distinguishable color bands. Applicants also assert, that by further evaluating the intensity of the bands, the band number can be manipulated by known detection techniques. Applicants arguments have been fully considered, however, are not found persuasive for the following reasons.

While Applicant may be pointing to a particular instance which may be different to a particular instance of Garini, the instances appear to be only "selectively" different by the way of the specification. The claims are broad enough to read on the invention as disclosed by Garini. As applicants cite particular elements of the specification, and certain possible embodiments of Garini, the limitations recited in the claims do not preclude the methods and compositions used for said methods as disclosed by Garini. For example, as Applicants assert in the response (page 8):

"...that the overlap of two differently labeled chromosome fragments bonded to the biopolymer will yield three distinguishable color bands"

However, this limitation is not specifically recited in the claims. Furthermore, with respect to this limitation, Garini does appear to address this overlap limitation in column 30, lines 27-39:

"Due to the random overlap of individual chromosome fragments in the five hybrid panels, the cohybridization of five differentially labeled groups (each group is represented by a single panel) of fragments would result in a banding pattern including bands that have pure colors, bands that include a combination of two, three, four, as well as five colors each, collectively 31 possible color combinations, which combinations can be distinguished using spectral imaging"

Although Garinin is broader, the disclosure does include each of the claimed limitations.

The rejection is maintained.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. The rejection of claim 25 under 35 U.S.C. 103(a) as being unpatentable over Garini et al., (U.S. Patent No. 5,817,462, October 6, 1998) in view of Kamensky et al. (U.S. Patent No. 5,107,422, April 21, 1992), in the Office Action mailed July 3, 2000, is maintained.

Applicants argue that the rejection should be withdrawn on the grounds that the rejection of Garini is inappropriate for reasons argued. Applicants also argue that the

Art Unit: 1631

art of Garini and Kamentsky are not consistent, and that Kamentsky could not be used to solve the problem. Applicants arguments have been fully considered, however, are not found persuasive for the following reasons.

Applicants arguments that the rejection should be withdrawn on the same grounds of Garini being inappropriate are not found persuasive for the reasons presented above. With respect to applicants arguments that the problem of background light is what Kamentsky solves, this limitation is not recited in the claims, nor communicated in such a way in the specification to draw this conclusion. Applicants claim calibrating "probes" which are fluorescence particles. Applicants claim is not limited to calibrating probes which are DNA probes that hybridize to chromosomal DNA, and are labeled with a fluorescent moiety, wherein the fluorescent moiety is a fluorescent particle. The fluorescent particles of Kamentsky are used for calibration purposes involving fluorescence imaging of cells and a cell's features, and are used to . Applicants method does specifically preclude this application.

The rejection is maintained.

Conclusion

7. No claims are allowable.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning the *merits* of this communication or earlier communications from the Examiner should be directed to Jeffrey S. Lundgren, whose telephone number is (703) 306-3221. The Examiner can normally be reached on Monday-Friday from 7:00 AM to 5:00 PM (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Michael Woodward, can be reached at (703) 308-4028.

Any inquiries of a *general* nature relating to this application should be directed to Ms. Pauline Farrier, Patent Analyst for Art Unit 1631, whose telephone number is (703) 305-3550.

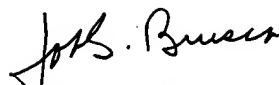
Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1631 using (703) 308-0294. Please notify the Examiner of incoming facsimiles prior to sending papers to the aforementioned fax

Art Unit: 1631

number. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).



Jeffrey S. Lundgren, Ph.D.


JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER